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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

26111 7590 03/12/2003

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EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/933,709	Applicant(s) MORRIS ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Continued Examination and Extension of Time, both received by the Office on December 9, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,234,695 to Hobbs *et al.*. Hobbs *et al.* disclose a vitamin E composition comprising a free flowing powder containing a vitamin E compound, and at least one flow agent selected from silicon dioxide, starch and others (c 9, claims 1 and 2). Further, Hobbs *et al.* teach that the vitamin E compound is present in between about 20-60% (c 3, l 61).

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant has amended the claims to include a proviso that the composition is "free is fatty acid esters of glycerin." Applicant argues that this overcomes the anticipation rejection. The examiner respectfully disagrees. Applicant claims a formulation directed to the production of dry, free flowing vitamin compositions. The

cited prior art also discloses dry, free flowing vitamin compositions. It is well known in the art that fatty acid esters of glycerin impart lubricity and permit formulations to have free flowing properties. Therefore, the presence of such additives are not detrimental to a free flowing composition. Applicant now claims composition free of fatty acid esters of glycerin. The burden is shifted to Applicant to establish, in declaration form, that said fatty acid esters of glycerin are detrimental to said formulation. Until such evidence has been provided, the above rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,603,143 to Schmidt (US '143). US '143 discloses vitamin active powders which are more free-flowing and stable than conventional vitamin powders. US '143 teaches that the composition comprises at least one fat-soluble vitamin material and a silicon containing material (c 1, l 38-45). US '143 also teaches that the vitamin be vitamin E, and further explains that vitamin E comprises a group of natural substances known as tocopherols (c 2, l 55-57). It is the position of the examiner that this disclosure reads on applicant's claim to mixed tocopherols. Furthermore, US '143 teaches that the silicon dioxide used in their composition has a density of around 0.2 g/cc (which is equivalent to 12.5 lbs./cu. ft.), and a particle size which passes through a 100 mesh sieve (c 3-4, table

1). (A 100 mesh sieve allows only particles which are smaller than 150 microns to pass through).

US '143 does not teach the specific particle size for the silica, as claimed by applicant. However, US '143 does teach that the particles are smaller than 150 microns. It is the position of the examiner that the determination of a particular particle sizes from within a broad range is within the skill of the ordinary worker as part of normal optimization. Additionally, US '143 does not teach the surface area of the silica. However, the burden is shifted to applicant to show that the silica disclosed by US '143 does not possess the same characteristics as the silica claimed by applicant. Lastly, US '143 does not specifically use the language mixed tocopherols in describing the vitamin to be used in their composition. However, as discussed in the anticipatory rejection, US '143 does teach that vitamin E is a group of natural substances known as tocopherol, and it further teaches that vitamin E can be used as the vitamin of the disclosed composition. Applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27).

Lastly, the reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. Furthermore, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the

applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Therefore, it is the position of the examiner that based upon applicant's own admission, the disclosure in US '143 teaching the use of vitamin E suggests the limitations of the instant claims. One of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E and silica. The expected result would be a free-flowing, fat-soluble vitamin powder with improved stability. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found persuasive. Applicants argue that the cited reference does not teach the claimed particle size. Applicants point out that the reference teaches agglomerates of silicon containing material. Applicants further assert that "although he agglomerate is said to consist of silicon containing material, silicon dioxide is said to be the primary component, with no other material specified... One of skill in the art would have no choice but to presume that if the non silica material(s) in these agglomerates are of any importance, they would certainly be specified... thus Applicants understand these agglomerates to be 100% silica." The examiner respectfully disagrees with these statements. The statement that

the agglomerates must be 100% silica is assumed by Applicant with no evidence, whatsoever, in the specification of the cited patent. Second, there is nothing in Applicant's instant claims to exclude the agglomeration of the silica particles. 300 microns is used to describe the size of the agglomerates, not the size of the silica particles which have agglomerated. Therefore, for the reasons stated in the above rejection, it remains the position of the examiner that the reference's teaching to silica particles smaller than 150 microns, and the known capability to manipulate particle size based on the specific needs of a particular formulation, still suggests the limitations of the instant claims. This rejection is maintained.

Rejection

Claims 18-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,234,695 to Hobbs *et al.*. Hobbs *et al.* are discussed above as teaching a vitamin E composition comprising a free flowing powder containing between 20-60% of a vitamin E compound and at least one flow agent selected from a group including silicon dioxide and starch.

Hobbs *et al.* do not teach that the vitamin is specifically mixed tocopherols. However, Hobbs *et al.* do teach that the vitamin can be selected from a group including vitamin E. Furthermore, applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27). Therefore, it is the position of the examiner that based upon applicant's own admission, Hobb's teaching of vitamin E suggests the limitations of the instant claims.

Hobbs *et al.* do not teach the specific density and surface area for the silica as claimed by applicant. However, it is the position of the examiner that with respect to the particular silica particle size, absent a clear showing of criticality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of normal optimization. The burden is shifted to applicant to show why the difference in particle size or surface area renders a different result.

Lastly, the reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. Furthermore, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

One of ordinary skill in the are would have been motivated to make a vitamin composition comprising vitamin E, silica, and corn starch, based on the teachings of Hobbs *et al.*. The expected result would be a free-flowing powder, non-sticking powder useful for pharmaceutical formulations. Therefore, this invention as a whole would have

been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been considered but are not found to be persuasive, for the reasons stated following the anticipation rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Tech Center 1600/AU 1615
March 7, 2003

THURMAN K. PAGE
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